the expected rate of false positives using standard cleanroom sterility-test work stations has been closer to 0.1%. Cloué and Wagner reported that the average false positive rate of sterility tests using cleanroom technology was 0.5% to 1.0% while that for isolation technology was 0% (6)

REFERENCES

1. Akers MJ, Larrimore DS, Guazzo, DM. Sterility testing. In: Marcel Dekker, ed. Parenteral Quality Control: Sterility, Pyrogen, Particulate, and Package Integrity Testing. 3rd ed. London: Informa Healthcare, 2003.
2. Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice. FDA, September, 2004, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070342.pdf. Accessed June 15, 2010.
3. Bowman FW. Application of membrane filtration to antibiotic quality control sterility testing. J Pharm Sci 1966; 55:818–821; The sterility testing of pharmaceuticals. J Pharm Sci 1969; 58:1301–1308.
4. Bugno A, Pinto TDA. The influence of incubation conditions in sterility tests. PDA J Pharm Sci Tech 2003; 57:399–409.
5. Council of the Pharmaceutical Society of Great Britain. Round Table Conference on Sterility Testing, London, 1963:B31.
6. Cloué P, Wagner CM. Sterility test isolators. In: Lysjford J, ed. Practical Aseptic Processing: Fill and Finish. Vol 2. Bethesda, MD: Parenteral Drug Association, 2009:86.

BIBLIOGRAPHY

European Pharmacopeia, Sterility Testing, 2.6.1

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC-PIC/S), Document PI-012–3, Recommendation on Sterility Testing

United States Pharmacopeia, Sterility Tests Chapter <71>. Rockville, MD: United States Pharmacoeial Convention, Inc.